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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,278	10/06/2006	Jacques Abraini	Serie 6132	6401

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Intellectual Property
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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,278	ABRAINI ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-44 and 46-59* is/are pending in the application.

4a) Of the above claim(s) *31-42 and 50-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43,44,46,47,48, 49,54-56,57, 58 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-30, and 45 have been cancelled. Claims 31-42, and 50-53 are withdrawn. Claims 57-59 are new. Claims 43, 44, 46-49, and 54-59 are under examination. Applicant's amendment has necessitated the new ground of rejection. Applicant has amended the independent claims to recite "consists of" thus narrowing the scope of the claims, defined the addiction in the independent claims and added 3 new claims. Accordingly, this action is FINAL.

Withdrawn rejections:

Applicant's amendments and arguments filed 8/28/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Claims 43, 44, 46-49 and 54-56 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lecourt et al. (US 2002/0033174) in view of Petzelt et al. (WO 00/53192) and Jevtovic-Todorovic et al. (reference C7 on the IDS submitted on 10/06/06) and Brooks (US 5846556) and claims 47-49 and 54-56 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mondain-Monval (US 4,820,258). Applicant has amended the claims to "consists of" which is not taught by the combination of references. The Examiner withdraws the rejections.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43, 44, 46-49, and 54-59 remain/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of amphetamine drug addiction, does not reasonably provide enablement for: 1) *prevention of addiction to amphetamines; and 2) the prevention and treatment of addictions to cocaine, tobacco, alcohol, cannabis, or other dependency-generating substances.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

Let the Examiner be clear: Applicant is not enabled for a gaseous inhalable medicament that consists of a mixture of from 20% to 32% by volume xenon and from 20% to 40% by volume nitrous oxide or a gas mixture that consists of from 10%-20% by volume xenon and from 45% to 50% nitrous oxide for the: 1) *prevention of addiction to amphetamines; and 2) the prevention and treatment of addictions to cocaine, tobacco, alcohol, cannabis, or other dependency-generating substances*. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or

direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that exposure to xenon or nitrous oxide immediately after pretreatment with d-amphetamine induces dose-dependent blocking of the sensitization process (specification page 10, lines 34-37 and specification page 11, lines 13-29, 35 through page 12, line 9). ***Thus Applicant appears to be enabled for those drug addictions that operate via the physiological pathway/ process described on pages 10-12 of the specification which reads on treating amphetamine addiction.*** However, Applicant is claiming prevention of addiction to amphetamines and the prevention and treatment of addictions to cocaine, tobacco, alcohol, cannabis, or other dependency-generating substances.

2) Nature of the invention

The nature of the invention is directed to a gaseous inhalable medicament comprising xenon and nitrous oxide for the treatment of drug addiction such as addiction to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances.

3) Relative level of skill possessed by one of ordinary skill in the art

MPEP 2141.03 states (in part), "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 167 LEd2d 705, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will

be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. At 1396, 82 USPQ2d at 1396. The "hypothetical person having ordinary skill in the art' to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art." Ex parte Hiyamizu, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The Board disagreed with the examiner's definition of one of ordinary skill in the art (a doctorate level engineer or scientist working at least 40 hours per week in semiconductor research or development), finding that the hypothetical person is not definable by way of credentials, and that the evidence in the application did not support the conclusion that such a person would require a doctorate or equivalent knowledge in science or engineering.). (emphasis added).

4) State of, or the amount of knowledge in, the prior art

The art teaches that administration of xenon to treat neurointoxications (Petzelt et al. (WO 00/53192). Jevtovic-Todorovic et al. teach a study designed to test the ability of nitrous oxide to protect neurons against excitotoxic.action of N-methyl-D-aspartate (reference C7 on the IDS submitted on 10/06/06) David et al. teach and suggest combining xenon and nitrous oxide to obtain optimal subcortical neuroprotection while minimizing the risk of adverse side effects and that the combination could be used in other brain diseases (reference C3 on the IDS submitted on 10/06/06).

5) Level or degree of predictability, or a lack thereof, in the art

The art teaches a laundry list of abused drugs and that there is no single treatment for all individuals with these **commonly abused drugs. (**commonly abused drugs; pages 1-6).

The MedlinePlus Medical Encyclopedia states that some people relapse after they have stopped using drugs and that drug educations programs may be helpful though none has proved effective in the long term for prevention of drug abuse and dependence (page 4 and 5 of 5).

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. The specification does not guide or provide direction for preventing and treating all forms of drug addiction.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to preventing or treating all forms of addiction. The specification is limited to describing exposure to xenon or nitrous oxide immediately after pretreatment with d-amphetamine induces dose-dependent blocking of the sensitization process (specification page 10, lines 34-37 and specification page 11, lines 13-29, 35 through page 12, line 9). However, nothing has been taught which would suggest that, for example, alcohol or tobacco or cocaine addiction can be treated or prevented.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct a myriad number of experiments comprising administration of a gaseous mixture to individuals who have physiological addictions to a laundry list of drugs with the hopes that the composition will perform as instantly claimed. This is especially difficult when the art teaches that some people relapse after they have stopped

taking drugs. *While Applicant appears to be enabled for those drug addictions that operate via the process described on pages 10-12 of the specification, drugs that operate via a different biochemical pathway would not benefit from such treatment.* Essentially, one of ordinary skill in the art has to figure out how to do this themselves. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to see if this invention is enabled.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." (Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997)).

Response to arguments:

Applicant asserts that: "claims 43 and 55 have been amended to indicate that the addition being prevented/treated is addition to amphetamines, cocaine, tobacco, alcohol, cannabis or other dependency-generating substances. Accordingly, Applicants maintain that claims 43 and 55 are now enabled." Respectfully, the Examiner cannot agree. It remains a leap of faith without a bridge of logic that Applicant's invention can prevent or treat any of the instantly claimed subject matter, except for the treatment of amphetamine addiction for which Applicant has some data in support, by administration of a gaseous inhalable medicament that consists of a mixture of from 20% to 32% by volume xenon and from 20% to 40% by volume nitrous oxide. One of ordinary skill in the art can not reasonably extrapolate the one amphetamine example to all the other species (alcohol, cocaine, tobacco, cannabis or other dependency-generating substances)

which have different chemical structures and different modes of action. In other words, the Examiner cannot reasonably extend the disclosed example in the specification to alcohol, cocaine, tobacco, cannabis or other dependency-generating substances because there is no trend in the exemplified data to allow that reasoning. There is no reasonable correlation between the data and the entire scope of the claim when viewed by the artisan because the species are structurally different from each other and function by different biological mechanisms. Applicant has only demonstrated data for amphetamines. In fact, it is almost *incredible* that Applicant can perform this method as claimed in view of the limited amount of data. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Conclusion

No claims are allowed.

Applicant is encouraged to contact the Examiner once this Office Action has been reviewed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/

Primary Examiner, Art Unit 1616